

2018 REACH REVIEW: A.I.S.E. Position

Sept 2018

On the 5th March 2018 the Commission published the 2nd review of REACH based on stakeholder opinions evaluating the effectiveness, efficiency, coherence, relevance and EU added value of the regulation. There is a broad consensus that REACH has been successful in achieving its aims. However, some opportunities for improvement were identified, with the Commission establishing 16 action points.

A.I.S.E. representing the EU industry for household, professional cleaning and maintenance products, summarises below, the sector's reaction to the action points of the REACH Review. We renew our commitment to further improve the REACH regulation and urge the Commission to:

- **Promote the work done on alternative methods to animal testing;**
- **Publicise the tools developed to harmonise supply chain communication (e.g. Use Maps Package, SUMIs)**
- **Further involve Downstream Users in the REACH process;**
- **Ensure a stable working environment for business and the actual functioning of the Single Market.**

1. *Knowledge and management of chemicals across the supply chain*

a. *Registration Dossier: Data gaps, updating, compliance*

A key point of the Commission's review was the incompleteness of registration dossiers. An important factor contributing to this deficiency is the lack of clarity regarding requirements for animal testing. One of the objectives of REACH is to reduce testing on animals; however, this is not backed by wider regulatory acceptance of alternative methods. Increased dossier completeness could be obtained if further guidance was provided by authorities and, in parallel, alternative methods were integrated into working practice. We highlight A.I.S.E.'s recent collaboration with the Netherlands to develop an [in-vitro test method](#) for eye hazard classification.

Improving and updating registration dossiers is also key, as the information provided through these is necessary to permit downstream users' products are used safely.

b. *Making dossier and substance evaluation processes more efficient*

With regards to evaluation, use of the grouping approach should be scrutinised. It is vital that REACH ensures the process is fully in line with scientifically based, comprehensive risk assessments. This method needs to be strengthened, fully considering the input from industry. Downstream users constitute a specific role in the supply chain, with their associated responsibilities. Therefore, they should be more involved in the compliance and evaluation steps (e.g. via public consultations or other means). They are equally affected by the evaluation process and are currently seeing the effects of many substances being restricted.

c. *Improving extended Safety Data Sheets*

A.I.S.E. agrees with the Commission's aim to improve the workability and quality of the extended Safety Data Sheets. The continuous increase in information which is currently being passed down the supply chain is one of the biggest challenges of downstream users. Extended SDSs are very

complex documents and often indicate unrealistic Risk Management Methods which do not take end-use application into account. The REACH Review Action 3 targets the simplification of the eSDS, considers the impact on mixtures, and encourages the creation of harmonised formats and IT tools. A.I.S.E. reinforces its commitment to contribute and provide expertise on these points. In this context, we stress the importance of supporting and advertising recent work by [DUCC](#) and other trade associations on the development of [SUMIs](#). Most importantly, all the tools that have already been developed to harmonise the communication within the supply chain, in particular the [Use Maps Package](#), should be widely publicised, promoted and used. It is vital, that adequate timelines are set out, to allow for these tools to become effective and that these remain at the focus of the solutions to be implemented.

2. Enhanced risk management

a. Simplification of authorisation and making restrictions more effective

A.I.S.E. welcomes the objective to have a more workable authorisation procedure. The Commission's aim to clarify requirements and make the process more efficient and predictable for applicants is key to industry stakeholders' need for a stable regulatory framework. Inclusion of socio-economic data in the RMOA stage (Regulatory Management Options Analysis) is also supported as it permits a holistic assessment to be carried out. A clarification of the precautionary principle that takes similar considerations into account in the risk management step would be equally supported. A.I.S.E. also calls for downstream users to be further involved in the RMOA process, to be able to comment on upstream steps such as dossier and substance evaluations. The sector has valuable data to contribute and is affected by the decision-making process at all levels. The RMOA process should be more defined and industry/ DU input should be explicitly incorporated. Finally, including input from Member States to simplify and harmonise the process would be valuable to improve timelines for evaluation and reducing discrepancies which currently translate into instability.

3. Coherence, enforcement and SMEs

a. Enhance enforcement with a focus on supporting SMEs

The REACH review clearly identified a key aim: to enhance enforcement while supporting SMEs. On this note, the requirements of REACH have resulted in large parts of R&D budgets being allocated to reactive innovation at the expense of proactive innovation. According to the EU Commission Cumulative Cost Assessment study (2016) [the overall legislation cost for the detergents and maintenance products industry](#) amounts to approximately: €670 million, corresponding to 33.4% of profits. This has hampered EU industry development, particularly impacting SMEs. A.I.S.E. encourages proposals to improve procedures of restriction and enforcement, if these focus on containing costs and ensuring industry competitiveness. In line with a single market approach, the target should be to remove discrepancies between legislation, align Member States assessments and reduce unnecessary regulatory burdens and ambiguity. The importance of clarity and coherence is particularly relevant. In fact, a key step to facilitating SMEs, is to ensure changes are implemented over an adequate timeframe and with consistency. Thus, allowing stakeholders to navigate and incorporate new frameworks and tools.

b. Interface of REACH and OHS: enforcement and coherence

A.I.S.E. is in favour of increased coherence between all legislation related to chemical substances. With regards to the OHS regulation A.I.S.E. welcomes the focus on ensuring the use of REACH tools like SDSs or exposure scenarios. This is a topic for which A.I.S.E. with its stakeholders have invested considerable resources to create the [SUMIs](#) (Safe Use of Mixture Information). These provide a bridge between REACH and OHS legislation, in order to make Exposure Scenarios information from substances understandable for professional end users of mixtures.

More information on the initiatives mentioned in this paper can be found on the [A.I.S.E. website](#).